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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,770	11/19/2001	Steven Leigh	2001-1087A	7884

513 7590 09/10/2004

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,770	LEIGH ET AL.	
	Examiner	Art Unit	
	Gollamudi S Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,13,15 and 17-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-13, 15 and 17-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 6-6-04 is acknowledged.

Claims included in the prosecution are 12-13, 15 and 17-26.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 12-13, 15 and 17-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Touitou (5,716,638) or Ribier (5,614,215) in view of the references of Mehta (5,811,119), Ganter (5,635,206) by themselves or in combination.

Touitou while disclosing phospholipid-containing compositions for application to the skin teaches the use of a combination of caffeine and salicylate (note the abstract and Example XVII on col. 10).

Ribier while disclosing liposomal compositions for application to the skin teaches that a combination of a keratolytic agent such as salicylic acid along with a liporegulating agent such as caffeine could be used (note the abstract, col. 6, lines 56-60).

What is lacking in these references is the teaching of formulating the composition in the form of a powder, which upon hydration forms liposomal structures. What is also lacking in these references is the preparation of liposomes first by forming a homogenous lipid mixture with the active agent and then hydrating with the aqueous medium.

Mehta discloses homogeneous powders containing phospholipids and retinoic acid. The powder is prepared without first forming the liposomes. The powder upon reconstitution forms liposomes (note the abstract and examples, example 1 in particular).

Ganter teaches that liposomal and proliposomal preparations containing the phospholipid can be prepared in a powder form for easy storage. The proliposomal preparations are prepared by milling a phospholipid and the lipophilic active agent without water. The powder when hydrated with water forms liposomes (abstract, col. 2, line 15 through col. 3, line 34 and examples).

The preparation of the liposomal compositions containing a hydroxy-acid and caffeine (a xanthine compound) taught by Touitou or Ribier by first forming homogeneous lipid mixture with the active agents and then hydrating with the aqueous medium would have been obvious to one of ordinary skill in the art since the references of Mehta, and Ganter, show that the liposomes can be prepared by first forming a homogeneous mixture of the phospholipid and the active agent (proliposomes) since the powders are stable for a long time. The newly added claims are included in the rejection because Ganter teaches milling (instant claim 24). Although Ganter does not

disclose the particle sizes (instant claim 26), it is deemed to be within the skill of the art to prepare suitable powders based on Ganter's teaching on col. 2 that the structure of the final product is influenced by milling speed. The preparation of the final product in the form of a lotion or cream is deemed to be within in the skill of the art since these are common cosmetic products as is also evident from Ribier (Examples 1 and 2).

3. Claims 12-13, 15 and 17-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Roux (6,103,259) or Hayward (5,585,109) in view of either Touitou (5,716,638) or Ribier (5,614,215), further in combination with Mehta or Ganter cited above.

Roux discloses liposomal preparations containing alpha hydroxy acids such as salicylic acid (note the abstract, col. 2, line 54 through col. 5, line 3). Roux however, does not teach the addition of a xanthine compound. Roux also does not teach the preparation of liposomes in the form of a powder.

Hayward similarly discloses liposomal compositions containing salicylic acid (note the abstract, and examples). Hayward however, does not teach the preparation of liposomes in the form of a powder and Hayward does not teach the inclusion of a xanthine compound along with salicylic acid.

Touitou while disclosing phospholipid-containing compositions for application to the skin teaches the use of a combination of caffeine and salicylate (note the abstract and Example XVII on col. 10).

Ribier while disclosing liposomal compositions for application to the skin teaches that a combination of a keratolytic agent such as salicylic acid along with a

liporegulating agent such as caffeine could be used (note the abstract, col. 6, lines 56-60).

The teachings of Mehta, and Ganter have been discussed above. The inclusion of caffeine in the compositions containing a salicylic acid of Roux or Hayward would have been obvious to one of ordinary skill in the art since the references of Touitou, and Hayward show the routine practice in the art of using a combination of salicylate and a Xanthine such as caffeine; one of ordinary skill in the art would expect the benefits of both agents from the resulting combination. The preparation of the liposomal compositions containing a hydroxy-acid and caffeine (a xanthine compound) by first forming homogeneous lipid mixture with the active agents and then hydrating with the aqueous medium to form liposomes, would have been obvious to one of ordinary skill in the art since the references of Mehta, and Ganter, show that the liposomes can be prepared by first forming a homogeneous mixture of the phospholipid and the active agent (proliposomes) since the powders are stable for a long time.

Applicant's arguments to the above rejections have been fully considered, but are not found to be persuasive. Applicant argues that the product in claim 12 is a homogeneous mixture and it forms liposomes when it is dispersed or dissolved in aqueous medium and not dried liposomes. These arguments are not found to be persuasive since the method of preparation disclosed by of Mehta involves the preparation of a homogenous mixture of the lipid and the active agent and does not involve the preparation of liposomes first and then dehydrate them. The reference of Mehta shows that powders can be prepared without making liposomes first and

therefore, one of ordinary skill in the art would be motivated to use Mehta's method for the active agents taught by Touitou or Ribier (caffeine and salicylic acid) with the expectation of forming liposomes only when an aqueous medium. Furthermore, a careful evaluation of the table on col. 2 of Ganter shows that grinding of the phospholipid and the lipophilic compound is performed without water (0 to 10 % water) and therefore, it is clearly evident from Ganter that the powder formed is homogeneous.

Applicant's arguments with regard to the retinoic acid taught by Mehta are not found to be persuasive since Mehta's homogenous powder preparation would be the same irrespective of which lipophilic compound is used as an active agent.

Note: in view of applicant's amendment the GB 2002 319 is withdrawn from the above rejections.

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK